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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,190	10/29/2001	Karin Connors	EP01-002C	7347
23500	7590 12/29/2004		EXAMINER	
PATENT DEPT EXELIXIS, INC. 170 HARBOR WAY			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
P.O. BOX 51	P.O. BOX 511			,
SOUTH SAN FRANCISCO, CA 94083-0511			DATE MAILED: 12/29/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/033,190	CONNORS ET AL.			
		Examiner	Art Unit			
		Georgia L. Helmer	1638			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	1) Responsive to communication(s) filed on <u>27 August 2004</u> .					
2a)⊠	This action is FINAL . 2b) ☐ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
5)□ 6)⊠	4) ☐ Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-4 and 7-14 is/are rejected. 7) ☐ Claim(s) 5 and 6 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.					
Application Papers						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
2) Noti	nt(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 er No(s)/Mail Date	4) Interview Summar Paper No(s)/Mail D 5) Notice of Informal 6) Other:				

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DETAILED ACTION

Status of the Claims

- 1. The Office acknowledges receipt of Applicant's Response dated 27 August 2004.
- 2. Applicant has amended claims 1 and 2, and added new claims 13 and 14. Claims 1-14 are pending, and are examined in the instant action.
- 3. This action is made FINAL necessitated by Applicant's amendment.
- 4. All rejections not addressed below have been withdrawn.
- 5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 6. Applicant's amendment to the specification as required in the Office Action of 27 February is acknowledged.

Claim Rejections - 35 USC § 112-2nd

7. Claim 2 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are also rejected

Claim 2 was rejected for the language 'hybridization under "high stringency conditions" which is indefinite, since the conditions need to be specified.

Applicant has amended claim 2, with the phrase "at about 5-10" below the Tm" and responds (Response, p. 5) that the amendment gives a more finite meaning for

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high stringency conditions, and asserts that the specification provides a description of the meaning of "high stringency conditions", citing the specification (p. 5, ¶ 0027, line 6) Applicant's traversal is unpersuasive. The cited specification recites a number of conditions and examples.

Claim Rejections - 35 USC § 112, first paragraph -written description

8. Claims 1-4 and 7-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record in the 27 February 2004 Office Action. This rejection is applied to new claims 13 and 14, which have the same written description problems as claims 1-4 and 7-12.

Applicant traverses saying primarily (Response, p. 6) claim 1 has been amended. Applicant further asserts (Response, p. 7) that the specification produces "an exemplary ANT1 amino acid sequence SEQ ID NO: 2 and the nucleic acid sequence SEQ ID NO: 1, how to determine % identity, how to determine the ANT1 phenotype, and describes fragments", and concludes that those of skill in the art would recognize Applicant's possession.

Applicant's traversal is unpersuasive. Applicant is making a conclusionary statement without evidentiary support. Applicant's cited information gives no information on the structure to function relationship of the 70%, 80% or 90% sequences. Applicant's amendment of claim 1 is solely to clarify the abbreviation ANT1. Furthermore, Example 14 of the Revised Interim Written Description Guidelines represent the instant situation, in which only a single protein of a single sequence was

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disclosed, which protein has a demonstrated function. Only claims drawn to proteins with at least 95% identity to that sequence were deemed adequately described.

Claim Rejections - 35 USC § 112 Enablement

9. Claims 1-4 and 7-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising SEQ ID NO: 1 or a polynucleotide encoding amino acid sequence SEQ ID NO: 2, does not reasonably provide enablement for the broad scope of the claims, as discussed in the Office Action of 27 February 2004. This rejection is applied to new claims 13 and 14, which have the same enablement problems as claims 1-4 and 7-12.

Applicant traverses saying primarily (Response, p. 7) the specification provide a description of the characterization of plants exhibiting ANT1 phenotype, that analysis confirmed the relationship of SEQ ID NO: 1 and the ANT1 phenotype, and that provides confirmation of the phenotype/genotype association, giving citations to specifics in the specification. Applicant further asserts that the specification gives a method for determining % sequence identity (Response, p. 8).

Applicant's traversal is unpersuasive. Applicant 's citations only give information for the 100% SEQ ID NOs. The phenotype is related only to the 100% sequences. No information is given for the 70%, 80% or 90% sequences. Applicant's assertions are insufficient to rebut the evidence provided by the Examiner to demonstrate the unpredictability inherent in the claimed invention.

Remarks

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- 10. No claims are allowed. SEQ ID NO: 1 and SEQ ID NO: 2 and sequences with at lease 70% identity thereto, are free of the prior art of record. Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helme

Patent Examine

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December 20, 2004

DAVID T. FOX